UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456
	CIVIL ACTION NO. 01-CV-12257-PBS
	Judge Patti B. Saris
THIS DOCUMENT RELATES TO ALL ACTIONS	

ASTRAZENECA PHARMACEUTICALS L.P.'s INDIVIDUAL MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS

193

INTRODUCTION

AstraZeneca Pharmaceuticals L.P. ("AstraZeneca")[1] respectfully submits this individual memorandum of law in support of its motion to dismiss the Master Consolidated Class Action Complaint (the "Complaint") pursuant to Rules 8(a), 9(b), 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure. Although the Complaint alleges that AstraZeneca manufactures and markets several drugs allegedly reimbursable under Medicare Part B including, but not limited to, Zoladex® (goserelin acetate implant), Nolvadex® (tamoxifen citrate), Tomudex® (raltitrexed) and Diprivan® (propofol), it is entirely devoid of any allegation that any named plaintiff purchased any drug other than Zoladex or that AstraZeneca engaged in any unlawful conduct with regard to any drug other than Zoladex.[2] Moreover, as set forth in the Consolidated Memorandum in Support of Defendants' Motion to Dismiss ("Defendants' Consolidated Memorandum"), the Complaint fails to state any claim against AstraZeneca, even with respect to Zoladex. Accordingly, for the reasons set forth below, as well as those in the Individual Memorandum of Law submitted by Defendant Bayer Corporation and Defendants Consolidated Memorandum, Plaintiffs' claims against AstraZeneca should be dismissed pursuant to Rules 8(a), 9(b), 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure.

ALLEGATIONS OF THE COMPLAINT

The Complaint alleges generally that AstraZeneca and the other defendants engaged in a fraudulent scheme to increase market share for their drugs by (i) artificially inflating the average wholesale price ("AWP") of their respective drugs; (ii) improperly encouraging health care providers to claim Medicare reimbursement for free samples; and (iii) offering other improper

---

[1] Zeneca Inc. and AstraZeneca PLC have not been served with the Master Consolidated Class Action Complaint. Accordingly, this memorandum is submitted on behalf of AstraZeneca Pharmaceuticals L.P. only. The entity named as AstraZeneca US does not exist.

[2] AstraZeneca does not concede that all of these drugs are, in fact, reimbursable under the Medicare Part B program.

inducements and incentives to healthcare providers and others. Compl. ¶¶ 157-172. Plaintiffs contend that, as a result of Defendants' fraudulent scheme, they and the classes they purport to represent overpaid for Defendants' drugs. Compl. ¶¶ 329-332; see Defs.' Consol. Mem. at 22-24 (summarizing allegations of Complaint).

The Complaint further attempts to assert claims based upon two sets of drugs: 1) drugs covered by the Medicare Part B program ("Class 1 Claims"), and 2) brand name drugs generally ("Class 2 Claims"). With respect to the Class 1 Claims, the Complaint alleges that "AstraZeneca manufactures and markets *several* drugs covered by Medicare Part B including, *but not limited to*: Zoladex® (goserelin acetate implant), Nolvadex® (tamoxifen citrate), Tomudex® (raltitrexed), and Diprivan® (propofol)." Compl. ¶ 62 (emphasis added). However, the Complaint contains no allegations of any unlawful conduct by AstraZeneca as to any Medicare Part B drug other than Zoladex. With respect to the Class 2 Claims, Compl. ¶¶ 166-172, the Complaint fails to identify any brand name drugs, let alone any AstraZeneca drugs. Moreover, there are no allegations in the Complaint that any plaintiff purchased any AstraZeneca drug other than Zoladex. Compl. ¶¶ 13-49.

ARGUMENT

The allegations of the Complaint demonstrate that Plaintiffs lack standing to assert any claims against AstraZeneca with respect to any drug other than Zoladex. Moreover, although Plaintiffs' Complaint sounds in fraud, it is utterly devoid of any allegations with respect to any drug other than Zoladex that satisfy the most basic notice pleading standard, much less the heightened pleading standard of Federal Rule of Civil Procedure 9(b). Since the Complaint also fails to state any claim against AstraZeneca with respect to Zoladex for the reasons set forth in Defendants' Consolidated Memorandum, the entire Complaint against AstraZeneca must be dismissed.

A. Because Plaintiffs Lack Standing to Assert Claims Against AstraZeneca with Respect to Any Drug Other than Zoladex, the Complaint Must be Dismissed

There are no allegations in the Complaint that any Plaintiff purchased any drug manufactured or marketed by AstraZeneca other than Zoladex. See Compl. ¶¶ 13-49. For the reasons set forth in Bayer Corporation's Individual Motion to Dismiss, which AstraZeneca adopts and incorporates herein, in the absence of any allegation that any of the named plaintiffs purchased any AstraZeneca drug other than Zoladex, Plaintiffs have failed to allege any injury traceable to any conduct by AstraZeneca as to any drug other than Zoladex. Accordingly, Plaintiffs' claims against AstraZeneca regarding any drug other than Zoladex must be dismissed for lack of standing pursuant to Federal Rule of Civil Procedure 12(b)(1).

B. Even if Plaintiffs Do Have Standing, the Allegations of the Complaint Fail to Satisfy the Most Basic Notice Pleading Standard, and Must Be Dismissed

Federal Rule of Civil Procedure 8(a) only requires that the complaint give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. Boston & Maine Corp. v. Town of Hampton, 987 F.2d 855, 864-65 (1st Cir. 1993). However, "[m]odern notions of 'notice pleading' notwithstanding, a plaintiff . . . is nonetheless required to set forth factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." Rumford Pharmacy, Inc. v. City of East Providence, 970 F.2d 996, 998 (1st Cir. 1992) (quoting Gooley v. Mobil Oil Corp., 851 F.2d 513, 515 (1st Cir. 1988). Rule 8(a) does not "entitle a plaintiff to rest on 'subjective characterizations' or conclusory descriptions of 'a general scenario which could be dominated by unpleaded facts.'" Arroyo-Santiago v. Garcia-Vicario, 187 F.3d 621, 1999 WL 551294, at *4 (1st Cir. 1999) (unpublished opinion) (quoting Dewey v. Univ. of New Hampshire, 694 F.2d 1, 3 (1st Cir.1982)).

Here, the Complaint lacks any factual allegations regarding Nolvadex, Tomudex, or Diprivan, or any other AstraZeneca drug alleged to be reimbursable under Medicare Part B, other

than Zoladex. Moreover, although the Complaint attempts to assert a second set of claims with respect to brand name drugs generally, it does not even name – much less assert any factual allegations with respect to – any brand name drug manufactured or marketed by AstraZeneca. Instead, Plaintiffs rely entirely on conclusory allegations of a general scheme to defraud by all Defendants to support their claims. However, by failing to specify any unlawful conduct by AstraZeneca with respect to: 1) any Medicare Part B drug other than Zoladex (Class 1 Claims); or 2) any AstraZeneca brand name drug on which the Class 2 Claims are based, the Complaint fails to provide AstraZeneca with fair notice of Plaintiffs' claims and the grounds upon which those claims rest. Accordingly, even if Plaintiffs somehow have standing to assert claims against AstraZeneca with respect to these drugs, any claims in the Complaint based on these drugs fail to satisfy the most basic notice pleading requirements of Rule 8(a) and must be dismissed.

C. Even if Plaintiffs' Allegations Satisfy Rule 8, the Allegations of the Complaint Fail to Satisfy the Heightened Pleading Requirements of Rule 9(b) and Must Be Dismissed

Federal Rule of Civil Procedure 9(b) states that: "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). Rule 9(b) requires specification of the time, place and content of an alleged false representation. Doyle v. Hasbro, Inc., 103 F.3d 186 (1st Cir. 1996); see also North Bridge Assocs., Inc. v. Boldt, 274 F.3d 38, 43 (1st Cir. 2001). "Even where such allegations are based on information and belief, supporting facts on which the belief is founded must be set forth in the complaint . . . even when the fraud relates to matters peculiarly within the knowledge of the opposing party." Hayduk v. Lanna, 775 F.2d 441, 444 (1st Cir. 1985) (quotations omitted).

The allegations of the Complaint fail to satisfy this heightened pleading standard. Plaintiffs allege generally that Defendants fraudulently inflated the published AWPs for their respective drugs above the price actually paid for those drugs by healthcare providers and others and further

increased the "spread" between AWP and actual acquisition cost by providing free samples and other improper inducements. Compl. ¶¶ 159, 162-66, 171. However, Plaintiffs fail to allege any specific facts supporting their Class 1 Claims with respect to any Medicare Part B drug other than Zoladex, relating to: (i) reported or published AWPs for these drugs; (ii) prices paid by health care providers or pharmacy benefit managers for these drugs; (iii) statements made by AstraZeneca to anyone regarding the AWPs for these drugs; or (iv) statements made by AstraZeneca to anyone regarding samples of these drugs or other inducements.[3] Moreover, with respect to their Class 2 Claims, Plaintiffs fail to allege any facts at all – much less specific facts – with respect to any AstraZeneca brand name drug on which their Class 2 Claims are based. Accordingly, the Complaint fails to meet the particularity requirement of Rule 9(b) and Plaintiffs' claims against AstraZeneca as to these drugs must be dismissed.[4]

CONCLUSION

For the reasons set forth above, as well as those stated in Defendants' Consolidated Memorandum and the Individual Memorandum of Law submitted by Defendant Bayer Corporation, AstraZeneca respectfully requests that all claims alleged against it in the Complaint be dismissed.

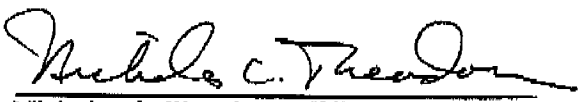
---

[3] Even with respect to Zoladex, Plaintiffs allegations fail to satisfy Rule 9(b), for the reasons set forth in Defendants' Consolidated Memorandum. Plaintiffs' conclusory allegation that AstraZeneca encouraged providers to bill for free samples is entirely unsupported by any specific facts as to the time, place and content of those statements. Moreover, there are no allegations with respect to AstraZeneca's alleged provision of "improper inducements" to health care providers. Accordingly, Plaintiff's claims against AstraZeneca based on Zoladex also should be dismissed under Rule 9(b).

[4] The Complaint also fails to satisfy Rule 8(a) and 9(b) for the additional reason that it fails to allege which AstraZeneca entity engaged in what conduct. It is insufficient for Plaintiffs to lump all AstraZeneca entities together and allege generally against all of them. Sebago, Inc. v. Beazer East, Inc., 18 F. Supp. 2d 70, 79 (1st Cir. 1998); see also Defs.' Consol. Mem. at 52 n.29. Accord Bower v. Weisman, 639 F. Supp. 532, 538 (S.D.N.Y. Apr. 8, 2002).

Dated: Boston, Massachusetts
November 4, 2002

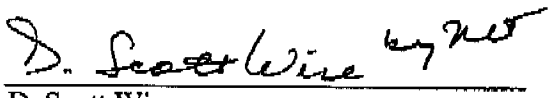
FOLEY HOAG LLP

By: 

Nicholas C. Theodorou (BBO # 496730)
Juliet S. Sorensen (BBO # 647255)

155 Seaport Blvd.
Boston, Massachusetts 02210
Tel: (617) 832-1000

DAVIS POLK & WARDWELL

By: 

D. Scott Wise
Kimberley D. Harris
Manisha M. Sheth

450 Lexington Avenue
New York, New York 10017
Tel: (212) 450-4000

Attorneys for AstraZeneca Pharmaceuticals L.P.